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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,765	09/28/2001	Dachuan Yang	S63.2-10002	2965

490 7590 01/13/2004

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/13/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/965,765

Applicant(s)

YANG ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,12-16,18-20,22 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 5-9,12-14,16,18,20 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,10,19,22 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Species of FIGS. 3 and 12 in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Objections***

2. Claim 1 was objected to for a minor informality. Corrections noted and the objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is dependent upon claim 3, which has been cancelled.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 10, 15, 19, 22, 28, 29, 32, 33, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 956 878 to Tachikawa et al.

Regarding claims 1 and 34, Tachikawa discloses a catheter comprising a tubular catheter shaft, the tubular catheter shaft having a proximal portion and a distal portion, the distal portion terminating in a distal tip, the distal tip comprising an inner matrix layer (4), an outer matrix layer (6), and at least one stripe (51) positioned between at least a portion of the inner matrix layer and the outer matrix layer (FIG. 5), the at least one stripe being substantially parallel to a longitudinal axis of the distal tip (FIG. 5), the inner matrix layer defined by at least one inner matrix material and the outer matrix layer defined by at least one outer matrix material different from the inner matrix material (Paragraph 0034), and the at least one stripe defined by at least one stripe material, the at least one inner matrix material and the at least one outer matrix material each having a predetermined hardness and the at least one stripe material having a predetermined hardness, the predetermined hardness of the at least one stripe material having a greater durometer value than the predetermined hardness of the at least one inner matrix material and the at least one outer matrix material (Paragraphs 0027-0033 and 0042-0044).

Regarding claim 2, Tachikawa discloses that the catheter defines a lumen (3).

Regarding claim 4, Tachikawa discloses that the at least one stripe material has a length substantially equal to that of the matrix (FIG. 5).

Regarding claim 10, Tachikawa discloses that the at least one stripe material is a plurality of stripes (FIG. 5).

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Regarding claims 15 and 19, Tachikawa discloses that each of the plurality of stripes is distributed between the inner matrix layer and the outer matrix layer in a uniform manner (FIG. 5).

Regarding claims 28 and 29, Tachikawa discloses that the at least one inner matrix material and the at least one outer matrix material are each selected from a group (Paragraphs 0027-0034) and the at least one stripe material is selected from a group (Paragraphs 0043-0044).

Regarding claim 32, Tachikawa discloses that the catheter is selected from the group consisting of dilatation catheters, guide catheters, over-the-wire catheters, rapid exchange catheters, and any combinations thereof (Paragraphs 0001-0002).

Regarding claim 33, Tachikawa discloses that at least a portion of the distal tip is radiopaque (Paragraph 0068).

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachikawa et al.

Tachikawa discloses that the hardness of the at least one inner matrix material and the at least one outer matrix material is 55D (Paragraph 0035). Tachikawa discloses the

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claimed invention except for the specific hardness of the at least one stripe material.

Tachikawa discloses the same materials as claimed. Tachikawa also states that the stripe material is rigid (Paragraph 0042) and the inner and outer matrix layers are made out of soft materials (Paragraph 0027). It would have been obvious to one having ordinary skill in the art to modify the hardness of the stripe material since such a modification would have involved the mere change in hardness of a material. The change in hardness is generally recognized as being within the level of ordinary skill in the art.

### *Response to Arguments*

9. Applicant's arguments with respect to claims 1, 2, 4, 10, 15, 19, 22, 28, 29, 30, 31, 32, 33 and 34 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

  
jrb



**JULIAN W. WOO**  
**PRIMARY EXAMINER**